

### **REMARKS/ARGUMENTS**

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed November 19, 2009. Claims 1-25 and 28-30 are pending, with claims 1-23 previously withdrawn from consideration. Claims 24, 25, and 28-30 have been rejected. Applicants respectfully traverse all adverse assertions and rejections presented in the Final Office Action. Favorable consideration of the following remarks is respectfully requested.

#### ***Claim Rejections – 35 USC § 112***

Claims 24, 25, 28 and 29-30 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner states that there is no teaching in the disclosure whether the “addition elements” as recited in claims 24 and 29, are part of the instant apparatus or are intended to be ingredients added to a mixture. Further, the Examiner states that if Applicants disclose that each “addition element” recited forms part of the apparatus, there is no support found in the specification for such an element. After careful review, Applicants must respectfully traverse the rejection.

Applicants respectfully point out that the addition elements of original claims 24 and 29 were elements of the claimed apparatus referred to as a “means”, and thus must be considered a structural component of the apparatus. For at least the same reason, support for the now-recited addition elements is present in the originally-filed claims. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

Claims 24, 25, and 28-30 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner has asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time that the application was filed, had possession of the claimed invention. In particular,

the Examiner appears to consider the claim terms “air injector”, “water supply”, and “addition element” to be new matter. Applicants respectfully traverse the rejection.

The Examiner has previously acknowledged that the level of skill and knowledge in the art is very high. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)(“The ‘written description’ requirement must be applied in the context of the particular invention and the state of the knowledge.... If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

With regards to the claimed air injector, the Examiner has specifically stated that “there is mention of “adding air”, but there is no explanation for how the air is added”. Applicants submit that the method of “how” to add air to gelatin is not required for an apparatus claim. Additionally, Applicants submit that adding air to a gelatin for foaming is known to one skilled in the art, as are various means for adding air. Therefore, at least implied support for the claimed air injector does exist. With respect to the claimed water supply, Applicants note that adding water to a mixture inherently requires a supply or source of that water. With respect to the claimed addition element, the Examiner states that “there is no support found for multiple addition elements”. Applicants respectfully disagree, and direct the Examiner’s attention to paragraph [0022] and the original claims. Paragraph [0022] states “sugars and/or polysaccharides may be added to the gelatin”, thus indicating at least three elements may be used within the mixture, and thus at least three addition elements may be present in the apparatus.

Accordingly, Applicants submit that the amendments presented on June 23, 2009 are indeed supported and respectfully request that the rejection be withdrawn.

### ***Claim Rejections – 35 USC § 103***

Claims 24-25 and 28-30 were rejected under 35 U.S.C. §103(a) as being

unpatentable over Pawelchak et al. (U.S. Patent No. 4,292,972) in view of Reich (U.S. Patent No. 6,706,690). After careful review, Applicants must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP 2143.03).

Independent claims 24 and 29 each recite, in part, “a heat source capable of heating the mixing chamber”. Pawelchak et al. do not appear to disclose or suggest such a feature. In fact, Pawelchak et al. do not appear to disclose or suggest heating the disclosed mixture, and expressly freeze dries the hemostatic article, as acknowledged by the Examiner. Pawelchak et al. also expressly discloses the use of sodium carboxymethylcellulose, which is known to be soluble in cold water. Accordingly, heat is unnecessary to mix and/or foam the material disclosed by Pawelchak et al.

Separately, claims 28 and 29 each recite, in part, “a dryer...operating at a temperature above a freezing point”. The Examiner advances Reich as teaching the formation of hemostatic materials using methods other than freeze-drying such as air drying, heat-assisted drying, molding, etc. However, as noted above, Pawelchak et al. do not appear to disclose or suggest heating the mixture. Pawelchak et al. also expressly disclose moving the material mixture to a different container prior to freeze-drying (see column 6, Examples 1 and 2). Applicants respectfully point out that the claimed dryer is separate from the claimed heat source. Both must be present in the apparatus. Therefore, even if the drying method disclosed by Reich were considered to disclose the claimed dryer, it cannot be considered as the claimed heat source since the dryer would not heat the mixing chamber.

The Examiner asserts that “Pawelchak et al. expressly teaches the formation of a hemostatic article which necessarily requires the use of the apparatus”. Applicants respectfully disagree. As noted above, the method disclosed by Pawelchak et al. does not appear to necessarily require a heat source capable of heating the mixing chamber. Therefore, the method taught by Pawelchak et al. does not necessarily require the use of the claimed apparatus.

Accordingly, neither Pawelchak et al. nor Reich, alone or in combination, appear

to disclose or suggest each and every element of independent claims 24 and 29, as is required to establish a *prima facie* rejection. Therefore, claims 24 and 29 are believed to be patentable over the cited references. Since claims 25, 28, and 30 depend therefrom and add additional elements thereto, Applicants believe that these claims are also patentable over the cited references. Withdrawal of the rejection is respectfully requested.

Claims 24-25 and 28-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ji et al. (U.S. Patent No. 5,894,022) in view of Szymaitis (U.S. Publication No. 2003/0194380). After careful review, Applicants must respectfully traverse this rejection.

Initially, the Examiner has acknowledged that Ji et al. do not teach each and every element of the claimed apparatus, specifically the injection of air to the composition, and has advanced Szymaitis as disclosing a reason to add air to the material mixture. However, Applicants have identified at least the following flaws in the asserted rejection:

The Examiner asserts that Ji et al. teach “the composition can be prepared by heating, mixing and dissolving reagents”, citing column 7, lines 55-67. Applicants note that Ji et al. do not appear to disclose a mixing chamber or a mixing element capable of stirring the contents of the mixing chamber. Ji et al. merely appears to disclose that a “mixture” exists. The composition of Ji et al. does not disclose or necessarily require the apparatus of the pending claims.

Additionally, Ji et al. do not appear to disclose a dryer operating at a temperature above freezing. Ji et al. do not appear to disclose drying the disclosed composition. Instead, Ji et al. appear to disclose that a precipitate is formed within the water bath when the disclosed emulsion is heated. Drying of the precipitate does not appear to be disclosed or suggested.

As acknowledged by the Examiner, Ji et al. also do not disclose or suggest injecting air into the composition for foaming, and has advanced Szymaitis for this purpose. However, Applicants note that the injecting air so as to foam a composition would appear to defeat the purpose of precipitating a matrix base by heating an emulsion, thus rendering the composition unsuitable for its intended purpose (MPEP 2143.01 V).

Furthermore, the Examiner has asserted that “Szymaitis teaches that hemostatic materials are activated by the addition of air”. Applicants respectfully disagree. Szymaitis appears to teach a periodontal regeneration, or bone growth, composition. Szymaitis does not appear to teach a hemostatic composition, or a method or apparatus for forming one. Additionally, “air” appears to be referenced only at paragraph [0027], which teaches “other materials activated by air, heat, light, or a catalyst could also be used as a thickener” for a periodontal regeneration composition, and at paragraph [0040], which teaches “gauze was soaked in an oxygenating solution. The solution releases oxygen. The oxygen causes hemostasis”. Nowhere does Szymaitis appear to disclose or suggest that “hemostatic materials are activated by the addition of air”, as asserted by the Examiner. Further still, neither Ji et al. nor Szymaitis appear to disclose or suggest an air injector as part of an apparatus for forming a hemostasis material, as in the pending claims.

For at least the reasons discussed above, Ji et al. and Szymaitis, alone or in combination, do not appear to disclose or suggest each and every element of independent claims 24 and 29, as is required to establish a *prima facie* rejection. Therefore, claims 24 and 29 are believed to be patentable over the cited references. Since claims 25, 28, and 30 depend therefrom and add additional elements thereto, Applicants believe that these claims are also patentable over the cited references. Withdrawal of the rejection is respectfully requested.

***Conclusion***

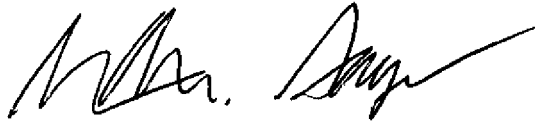
In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Eduardo Chi Sing et al.

By their Attorney,

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Glenn M. Seager, Reg. No. 36,926  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
[Glenn.Seager@cstlaw.com](mailto:Glenn.Seager@cstlaw.com)  
Tel: (612) 677-9050  
Fax: (612) 359-9349